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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,638	08/19/2003	Howard R. Levin	3659-70	3724

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,638	LEVIN ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-63 and 72-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *58-63, 72/58, 72/59, 72/63, 73/58, 73/59, 73/63, 74/58, 74/59, 74/63, and 76-78* is/are allowed.

6)☒ Claim(s) *56,57,72/57,73/57,74/57, and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/19/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

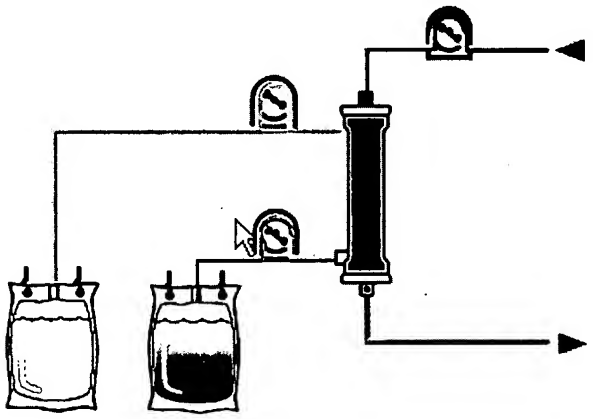
Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

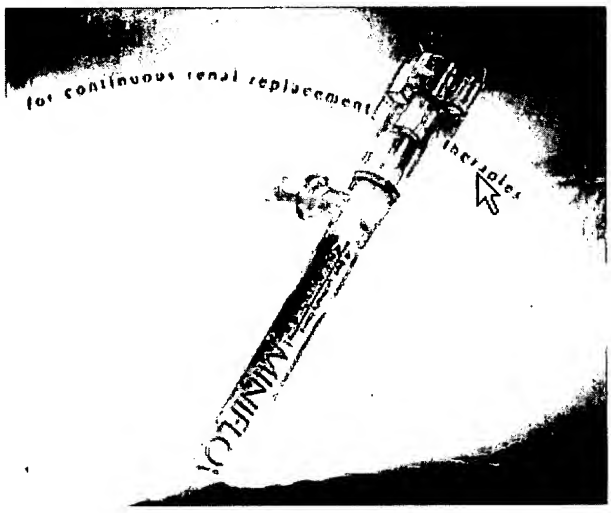
2. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over a disclosure of the Hospal Miniflow 10 (1997 study from Gouyon et al, showing the existence of the Miniflow 10 as early as 1997, accompanied by pages of internet data from Gambro-Hospal, showing Miniflow 10 specifications) in view of US 4,197,196 to Pinkerton.

In the documentation, the Miniflow is disclosed and shown as having a hollow fiber surface area below $0.1m^2$, blood input and output lines with pump, and dialysis input and output lines with pumps (see CVVD illustration, below).



CVVHD illustration using Hospal Miniflow 10

The hollow fibers are arranged in a bundle in a straight housing (see diagram). The Miniflow is also disclosed as being capable of use within a hemodialysis procedure, including the steps of flowing blood through the filter membrane in countercurrent to a dialysis fluid (see Hospal page entitled "Pump-assisted renal replacement therapies). As such, the Hospal filter apparatus has a filter membrane surface comprising the interior of the hollow fibers.



Miniflow 10, showing conventional hollow fiber bundle

The Miniflow documentation fails to disclose the rate of ultrafiltrate withdrawal. However, Pinkerton discloses a hemodialysis system that withdraws waste or ultrafiltrate at a rate of 5-15mL/min, or 0.3-0.9L/hour according to patient parameters in order to avoid adverse affects from withdrawal rates that are too slow or too quick (see column 1, lines 27-42). Therefore, it would have been obvious to employ the filtrate

withdrawal rate disclosed by Pinkerton in the filtration methods disclosed by the prior art in order to prevent adverse patient effects, as taught by Pinkerton.

3. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over a disclosure of the Hospal Miniflow 10 (see pages of internet data, accompanied by 1997 study from Gouyon et al, showing the existence of the Miniflow 10 as early as 1997), in view of US 4,666,426 to Aigner, further in view of US 4,197,196 to PInkerton.

With regard to claim 57, the Miniflow is disclosed and shown as having a hollow fiber surface area below 0.1m^2, blood input and output lines with pump, and dialysis input and output lines with pumps (see CVVD illustration). The hollow fibers are arranged in a bundle in a straight housing (see diagram). The documentation does not disclose the dimensions of the housing, but the Miniflow appears to be less than 20cm long and less than 1.5cm in diameter. The Miniflow is also disclosed as being capable of use within a hemodialysis procedure, including the steps of flowing blood through the filter membrane in countercurrent to a dialysis fluid (see Hospal page entitled "Pump-assisted renal replacement therapies). As such, the Hospal filter apparatus has a filter membrane surface comprising the interior of the hollow fibers.

With regard to applicant's claim language drawn to the volume of the container comprising less than 2% of the patient's cardiac output, such a size limitation comprises an obvious variation of the device. See MPEP 2144.04. In the instant case, the Hospal cartridge is capable of holding less than 2% of a patient's cardiac output, since patients of various size, and corresponding various blood volume and cardiac output, may be treated by the device.

The Miniflow documentation does not disclose the molecular weight of the molecules filtered, but Aigner discloses a filtration membrane that blocks the passage of particles with a molecular weight greater than 60,000, which corresponds to 60,000 Daltons (see column 5, lines 45-50). The filter membrane is made with such small pore sizes in order to facilitate ultrafiltration (see column 5, lines 39-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hollow-fiber filter membranes of the Hospal Miniflow 10 to block passage of molecules of about 60,000 Daltons as disclosed by Aigner in order to provide ultrafiltration, as taught by Aigner.

Neither the Miniflow documentation nor Aigner disclose the rate of ultrafiltrate withdrawal. However, Pinkerton discloses a hemodialysis system that withdraws waste or ultrafiltrate at a rate of 5-15mL/min, or 0.3-0.9L/hour according to patient parameters in order to avoid adverse affects from withdrawal rates that are too slow or too quick (see column 1, lines 27-42). Therefore, it would have been obvious to employ the filtrate withdrawal rate disclosed by Pinkerton in the filtration methods disclosed by the prior art in order to prevent adverse patient effects, as taught by Pinkerton.

With regard to applicant's claim 56 drawn to the operation of a filtrate pump to control flow rate and concentrate the blood, Pinkerton discloses that flow rates are controlled by mechanically actuated pistons that control flow rate and the removal of waste fluid from the patient, thereby concentrating the blood (see columns 4-6).

With regard to claims 72 as dependent on claim 57, 73 as dependent on claim 57, and 74 as dependent on claim 57, Aigner discloses that a filter excluding passage of

particles greater than 20,000 Daltons may be employed in some embodiments, meeting the limitations of the claims.

Allowable Subject Matter

4. Claims 58-63, 72 as dependent from claim 58, 72 as dependent from claim 59, 72 as dependent from claim 63, 73 as dependent from claim 58, 73 as dependent from claim 59, 73 as dependent from claim 63, 74 as dependent from claim 58, 74 as dependent from claim 59, 74 as dependent from claim 63, and 76-78 are allowed.

5. The following is a statement of reasons allowance: The prior art fails to disclose or suggest the methods as claimed by applicant.

With regard to the independent claims, the prior art fails to suggest a method of ultrafiltration comprising the combination of the steps of withdrawal and return of blood to a patient while utilizing a filter membrane with the claimed surface area, wherein the filtrate and/or the blood is moved through the filtration circuit at the rates and within the times claimed by applicant, along with the other steps and limitations of the claims.

In particular, the prior art fails to disclose a method for filtering blood comprising the step of using the claimed filter and a) withdrawing the blood at a rate of 10/60mL/min for an *ultrafiltration* procedure on *withdrawn blood*, or b) passing the blood through the filtration circuit in less than 2 minutes, or c) flowing the blood in order to achieve the claimed shear rate, along with the other steps and limitations of the claims.

Response to Arguments

6. Applicant's amendment and comments filed 26 February 2007 have been entered and fully considered.

7. As a result of applicant's amendment to the previously allowed claims 56 and 57, examiner conducted a new search that revealed previously undiscovered art which is hereby applied to the claims.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
18 April 2007

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4-28-07